

## **REMARKS/ARGUMENTS**

### **I. Status of the Claims**

Claims 113-121 and 123-165 are pending.

### **II. The Amendments Herein**

No new matter is added by the amendments herein.

The amendment to the specification updates the status of the referenced application, in compliance with MPEP 608.01 I A 1.

Claim 113 has been amended to correct a minor typographical error.

No new issue for search or examination is raised, and entry of the amendments at this time is respectfully requested.

### **III. The Office Action**

The Action rejects the claims on several grounds. They are addressed below in the order in which they are presented in the Action.

#### **A. The Drawing Correction**

The corrected version of Figure 1 submitted with Applicants' previous response was not accepted because it was not accompanied by a second sheet showing the changes in red ink. Accompanying this paper is a replacement copy of the corrected version of Figure 1 and a copy of the previous Figure 1 showing in red ink the correction to Figure 1. Action, at page 2. The red marked up copy is believed to obviate the objection.

#### **B. Sequence Requirements**

The Action indicates that the application is not in sequence compliance because amended Figure 1 was not accompanied by a red marked up copy. Action, at page 2. The accompanying red marked up copy of Figure 1 is believed to obviate the objection.

**C. Incorporation by Reference of Information in Figure 1 as Corrected**

The Action rejects claims 113-121 and 123-165 under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter which was not described in such a way as to indicate that the inventors had possession of the invention at the time of filing. In this regard, the Action states that the Applicants have to amend the disclosure to incorporate the amendatory material by reference without accompanying it with a declaration or affidavit, as allegedly required. Action, at pages 3-4.

The Action states that Applicants are required to amend the disclosure to incorporate essential information. Applicants respectfully note that the correction of Figure 1 makes the appropriate correction of the application's disclosure.

The Action further asserts that the copy of email correspondence between Dr. Chowdhury, an inventor of the present invention, and Dr. Karen Clark, of GenBank, was not accompanied by a declaration or affidavit indicating that the amendatory material consists of the same material incorporated by reference. To expedite prosecution, this Amendment is accompanied by a Declaration of Dr. Ira Pastan. The Declaration states that the change of the nucleotide at position 61 from "a" to "t" changes the encoded amino acid from "L" to "I" and therefore the amendatory material is the same material as that incorporated by reference. Accordingly, the Declaration is believed to obviate the rejection.

**D. Incorporation by Reference of Positions for Cysteines for Disulfide Bonds**

The Action maintains the rejection of claim 120 under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter which was not described in such a way as to indicate that the inventors had possession of the invention at the time of filing. Action, at page 4. The rejection concerns the incorporation of U.S. Application No. 08/077,252 at page 8, lines 24-25 of the present specification, in the definition of "antibodies." The Action notes that the incorporation of the '252 application occurs in a definition of the term "antibody," and is directed to genetically engineered forms, including dsFvs. The Action then states: "The passage does not

incorporate the residues that would be altered to form the dsFv. There is nothing in the passage that limits one to only altering the recited residues in claim 120 to cysteines." Action, at page 4.

The Action is correct in its observation about where in the specification the cited incorporation of the '252 application appears. The Action is also correct that the definition of "antibody" in the present specification does not mention the specific residues to be modified to cysteines. According to MPEP §608.01(p) I.A., at page 600-79, left column, however, "[a]n application for a patent when filed may incorporate 'essential information' by reference to . . . (3) a pending U.S. application." "Essential information," in turn, is defined "as that which is necessary to . . . (2) provide an enabling disclosure of the claimed invention." *Id.*

Applicants respectfully note that the incorporation of the '252 application was of the whole application. The '252 application provides a written description for everything that application teaches, including specific residues particularly suitable for replacement with cysteines to create dsFvs. Thus, even conceding (for the sake of argument) that the Action is correct that the definition of antibody into which the present specification incorporated the '252 application did not refer to the positions to be modified, that is not limiting with regard to the material incorporated. Applicant is still entitled, under MPEP §608.01(p) I A, to incorporate any element of the '252 application, including the positions of the residues cited in claim 120, as essential material. Applicants therefore respectfully submit that claim 120 as presented is fully supported and meets the requirements of 35 U.S.C. § 112, first paragraph.

The MPEP also provides that there is no need to amend the present disclosure to recite the incorporated material from the incorporated '252 application. MPEP §608.01(p)(I)A 1 provides, at page 600-80, left column, first full paragraph, that in the event that an application that incorporates essential material by reference to a pending application, the Examiner, prior to allowance "shall determine if the referenced application has been published or issued as a patent." If it has, the Examiner "shall enter the . . . U.S. Patent No. of the referenced application in the specification of the referencing application." The applicants is only required to amend the disclosure of the referencing application to include the material incorporated by reference if the referenced application has not issued as a patent. *Id.* Since the '252 application has issued as a

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patent, amendment of the disclosure of this application is accordingly not required. Applicants have amended the paragraph of the specification at which the incorporation occurs to comply with the requirement to enter the U.S. Patent Number.

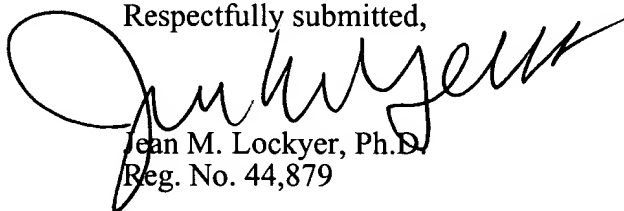
In brief, even if the Action's position is otherwise correct, Applicants submit that they are authorized under the MPEP to incorporate into the present disclosure the locations of preferred residues from the '252 application as necessary to support claim 120 as presented. Applicants respectfully request reconsideration, and withdrawal, of the rejection of the claim under §112.

#### CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, he is invited to telephone the undersigned at 415-576-0200.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Jean M. Lockyer", is written over the typed name and registration number.

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